

***PRESENTATION:***

**THE EXPERIMENTAL USE EXCEPTION:  
A JAPANESE PERSPECTIVE**

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Under Japanese patent law, the typical issues with respect to experimental use are similar to those in other countries. Let me first describe two basic features in the Japanese patent system. First, Japanese patent law provides a statutory exception to experimental use; however, there is no provision that explicitly defines the meaning of “experiment.” Second, it is necessary to go through highly complicated application procedures in order to obtain government approval for producing pharmaceuticals.

Under Japanese Pharmaceutical Affairs Law, however, there is an abbreviated application procedure for generic pharmaceuticals that is much more simplified than that for new drugs. Whereas a completely new drug is required to test from Phase I to Phase III in a very rigorous manner, a generic pharmaceutical needs only a one-phase test called the “Biological Equivalence Test.” This Biological Equivalence Test is required to prove only that the tested drug has ingredients that have an effect equivalent to that of an approved drug. The Biological Equivalence Test is quite similar to ANDA in the United States. It should be noted, however, that even with this simple Biological Equivalence Test application, it takes about two years to obtain approval from the Ministry of Public Health. Therefore, whether such a test can be executed during the term of the patent becomes a critical issue for generic drug makers because it will determine when they can place their products on the market – either at the time the patent expires or two years later.

In Japan, issues of this kind have always potentially existed, but it was not until the late 1990s that a number of suits suddenly were brought before the court. For background, note that substances themselves were not included in patent rights before 1975 in Japan. When a new material was invented, patent rights could not be obtained for the chemical substance itself but only for the means or equipment used in the course of production. In 1975, chemical substances came to be included in patent rights in Japan. Since then, a number of patents have been issued. In those days, patent law protected the patent right for a term of fifteen years from the date of issuance. As a result, patents issued in the early 1980s finished their term of protection in the late 1990s, one after another. This was a great business opportunity for generic drug makers – they dared to execute Biological Equivalence Tests before patents expired and asked the Ministry of Public Health for

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production approval. Naturally, pioneer drug makers brought a number of suits against the generic drug makers. Under those circumstances, in the late 1990s, suddenly this issue came into focus.

Under Japanese Patent law, Section 69.1 provides that patent rights shall not extend into experimental research. This provision was first introduced in 1909 and has remained valid since then. This situation differs from that of other countries such as Germany, where there had not been a statutory exception for experimental use until 1981 (as discussed by Dr. Goddar). Currently, the United States still has no such statutory exception.

It is clear why Japan employed the statutory exception relatively early compared to other countries. At that time, Japan was still a developing country. Reverse engineering was needed in all fields of technology. The experimental use exception was recognized explicitly so that people could develop new technology. In this respect, Section 69 differs from the Hatch-Waxman Act in the United States, which applies not to every technology but only to pharmaceutical technology and other neighboring fields.

In addition, since 1987, the Japanese patent law has provided a patent term extension system. In contrast to the statutory exception just described, the term extension system was introduced as a direct defense of the Hatch-Waxman Act in the United States. The patent term extension system applies to pharmaceutical products and agricultural chemicals. It provides that a patentee who fails to enjoy patent rights for more than two years due to the governmental approval process of ensuring the safety be given up to a five-year term extension. This revision brought benefits to brand name drug companies.

The 1987 change in Japanese patent law addressed only term extension. While the Hatch-Waxman Act made it easier for generic drug makers to enter the market by filing an ANDA, no such statutory compensation for generic drug makers was required in Japan because a similar procedure, the Biological Equivalence Test, already had been established. However, Section 69, present since 1909, does not explicitly allow experimental use in order to pass regulatory safety tests. Accordingly, whether the Biological Equivalence Test would be allowed during the patent term became a critical issue in dispute.

In April of 1999, the Japanese Supreme Court ruled that the Biological Equivalence Test shall be regarded as an experiment under Section 69. Therefore, infringement is not found if the Biological Equivalence Test is executed during the patent term. The Court's reasoning was three-fold. First, the essence of the patent system is that anyone can fully utilize the invention after the patent expires. Thus, the system serves the interest of society on the whole. Second, assuming that the Biological Equivalence Test is not regarded as an "experiment" and therefore is prohibited during the patent term, generic drug makers would be forced to waste a substantial amount of time after the patent expired. Third, this time period would allow the patent owner to enjoy market exclusivity beyond the patent term. The Court believed that such consequences would disregard the policies of the patent system.

Prior to the Supreme Court decision, the Tokyo District Court and the Tokyo High Court had also reasoned that a test like Biological Equivalence Test could provide technological progress, or that a more competitive market is in the public interest. I criticized such reasoning at this conference three years ago, and it may have influenced the reasoning of the Supreme Court. The result of their decision is very liberal and generous for

experimental use – even in the case of the third category of Dr. Goddar's report, where the indication of the existing drug is followed without any technological development.

With that Supreme Court decision, the issue came to an end as a matter of Japanese patent law. I have paid special attention, however, to the consequences of the World Trade Organization's dispute settlement procedure, which was brought by European communities and membership countries against Canada almost simultaneously with the Supreme Court decision in 1999. The panel found a similar provision of Canadian patent law was not permitted under the TRIPS Agreement. It meant that the Japanese Supreme Court decision would be found not in conformity as well, by the same reasoning. Unfortunately, that result was disappointing to me because I expected a dramatic turn.

In my view, the Japanese Supreme Court decision is consistent with Articles 27 and 30 of the TRIPS Agreement. The decision seemed to apply only to pharmaceuticals. The TRIPS Agreement, according to the panel report of May 2000, and approved by the dispute settlement body, maintains a strong position of anti-discrimination among patent rights in technology. Moreover, this anti-discrimination policy covers not only *de jure* discrimination but also *de facto* discrimination. Accordingly, the Supreme Court decision should be applied to any field of technology. For example, in Japan, architectural improvements in earthquake resistant building are very important. Among these improvements is a technology that makes buildings earthquake resistant by inserting rubber between fundamental structural parts. Because it enhances the safety of the building as a whole, such technology often is required to obtain authority and permission for actual use. Although the patent term extension system does not apply to such technologies, the Supreme Court decision must apply to them. In effect, a construction company is allowed to make full use of the patented invention of its competitor for the purpose of getting the authority's permission, without any compensation to the competitor who holds the patent rights.

Under Article 30, all patent owners must have the legal opportunity to exclude others from the market of the patented product during all or virtually all of the twenty-year period of market exclusivity. Protecting this legal opportunity, however, is not included in the meaning of legitimate interest under Article 30; therefore, this construction is consistent with the view of the Supreme Court as described previously. Such a view is permitted by the panel report, even though it is not promoted.

According to the Japanese Supreme Court, although generic drug makers are able to perform the Biological Equivalence Test in order to obtain production approval from the Ministry of Public Health before the patent expires, there is no provision that allows stockpiling during the patent term. Generic drug manufacturers are not permitted to produce such drugs for the purpose of sale. As to this last point, there is no dispute.

However, what happens when a generic drug maker produces a drug for the purpose of sale in reality? Where should the stored products be destined? Some think that, although the drugs were produced in violation of patent rights, when the patent expires its effect on the products would become invalid; therefore, selling these products should be permitted after the expiration of the patent. The issue is not actively disputed; this view appears to be a majority view in academic opinions and by implication of the courts in Japan.

Practically, it would be very difficult for a patent owner to find out whether a generic drug maker has actually produced and stored a product for the purpose of sale after patent

expiration. Even if the patent owner could find this out, given that the suit would take several years in Japan, it is very likely that the patent would expire before the suit ends. In effect, this view would be equivalent to allowing a stockpiling exception, which the panel report was expressly against. In my opinion, taking the view previously described is inconsistent with the purported view of the panel report.

In conclusion, although the Supreme Court decision itself is not inconsistent with the panel report, the dispute between the European communities and Canada may result in certain restraints on the interpretation of Japanese Patent Law in the near future.

Thank you very much.